

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0105  
Inventors: Ali et al.  
Serial No.: 09/700,700  
Filing Date: November 20, 2000  
Examiner: Davis, Minh Tam B.  
Group Art Unit: 1642  
Title: A Novel Method of Diagnosing,  
Monitoring, and Staging Prostate Cancer

I, Kathleen A. Tyrrell, Registration No. 38,350,  
certify that this correspondence is being deposited  
with the U.S. Postal Service as First Class mail in  
an envelope addressed to the Commissioner for Patents  
P.O. Box 1450, Alexandria, VA 22313-1450

On this date: April 5, 2004

Kathleen A. Tyrrell  
Kathleen A. Tyrrell Registration No. 38,350

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

( ) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified

04/19/2004 SLUANG1 00000006 501619 09700700

01 FC:1806

180.00 DA

application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

(XX) In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

( ) Certification in Accordance with §1.97(e) is attached hereto; or

(XX) Authorization to charge Deposit Account No. 50-1616 the fee of \$180.00 as set forth in §1.17(p) is provided.

( ) In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I) (1).

(XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

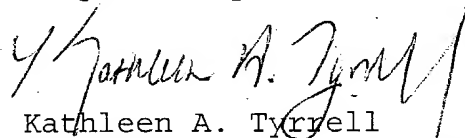
( ) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

( ) The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,

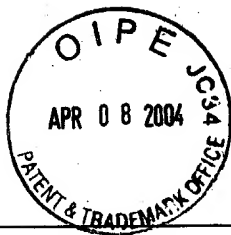


Kathleen A. Tyrrell  
Registration No. 38,350

Date: April 5, 2004

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515



Sheet 01 of 02

Form PTO-1449 Modified  
List of Patents and Publications  
Cited by Applicant  
(Use several sheets if necessary)

U.S. Department of Commerce

Docket No.  
DEX-0105Serial No.  
09/700,700Applicant  
Ali et al.Filing Date  
November 20, 2000Group  
1642

## U. S. PATENT DOCUMENTS

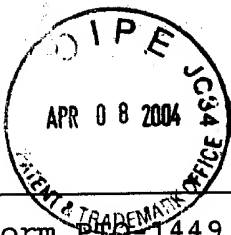
Examiner Initial		Document No.	Date	Name	Class	Subclass
	CA	2002/0022248	2-21-02	Xu et al.	435	69.1

## FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES NO	
	CB	WO 00/04149	27-1-00	PCT	x	
	CC	WO 99/64594	16-12-99	PCT	x	

EXAMINER

DATE CONSIDERED



Sheet 02 of 02

Form PTO-1449 Modified		Docket No. DEX-0105	Serial No. 09/700,700
List of Patents and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Ali et al.	
		Filing Date November 20, 2000	Group 1642
U.S. Department of Commerce			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
DA	Abate-Shen et al., "Nkx3.1; Pten Mutant Mice Develop Invasive Prostate Adenocarcinoma and Lymph Node Metastases <sup>1</sup> ", Cancer Research 2003 63(14):3886-3890		
DB	Bierberich et al., "Prostate-specific and Androgen-dependent Expression of a Novel Homeobox Gene", J. Biol. Chem. 1996 271(50):31779-31782 reprinted as pages 1-10		
DC	He et al., "A Novel Human Prostate-Specific, Androgen-Regulated Homeobox Gene (NKX3.1) That Maps to 8p21, a Region Frequently Deleted in Prostate Cancer", Genomics 1997 43:69-77		
DD	Herbrand et al., "Transcription factors Nkx3.1 and Nkx3.2 (Bapx1) play an overlapping role in sclerotomal development of the mouse", Mechanisms of Development 2002 117:217-224		
DE	Kim et al., "Nkx3.1 Mutant Mice Recapitulate Early Stages of Prostate Carcinogenesis <sup>1</sup> ", Cancer Research 2002 62:2999-3004		
DF	Kim et al., "Cooperativity of Nkx3.1 and Pten loss of function in a mouse model of prostate carcinogenesis", Proc. Natl. Acad. Sci. USA 2002 99(5):2884-2889 reprinted as pages 1-10		
DG	Prescott et al., "Isolation and Androgen Regulation of the Human Homeobox cDNA, NKX3.1", The Prostate 1998 35:71-80		
DH	Sciavolino et al., "Tissue-Specific Expression of Murine Nkx3.1 in the Male Urogenital System", Developmental Dynamics 1997 209:127-138		
DI	NCBI Genbank Accession U80669 [gi:1732377] 10 December 1996 - 3 June 1999 with Revision History		
EXAMINER		DATE CONSIDERED	



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0105

Inventors: Ali et al.

Serial No.: 09/700,700

Filing Date: November 20, 2000

Examiner: Davis, Minh Tam B.

Group Art Unit: 1642

Title: A Novel Method of Diagnosing,  
Monitoring, and Staging Prostate Cancer

I, Kathleen A. Tyrrell, Registration No. 38,350,  
certify that this correspondence is being deposited  
with the U.S. Postal Service as First Class mail in  
an envelope addressed to the Commissioner for Patents  
P.O. Box 1450, Alexandria, VA 22313-1450

On this date: April 5, 2004

  
Kathleen A. Tyrrell Registration No. 38,350

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

( ) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified

04/19/2004 SLUANG1 00000006 09700700

01 FC:1806 180.00 DA

application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

(XX) In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

( ) Certification in Accordance with §1.97(e) is attached hereto; or

(XX) Authorization to charge Deposit Account No. 50-1616 the fee of \$180.00 as set forth in §1.17(p) is provided.

( ) In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I) (1).

(XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

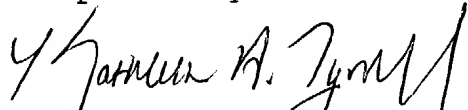
( ) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

( ) The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,



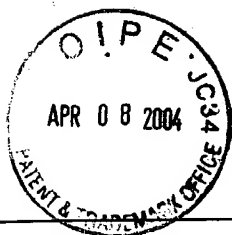
Kathleen A. Tyrrell  
Registration No. 38,350

Date: April 5, 2004

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515





Sheet 01 of 02

<b>Form PTO-1449 Modified</b> List of Patents and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce	Docket No. <b>DEX-0105</b>	Serial No. <b>09/700,700</b>
	Applicant <b>Ali et al.</b>	
	Filing Date <b>November 20, 2000</b>	Group <b>1642</b>

## U. S. PATENT DOCUMENTS

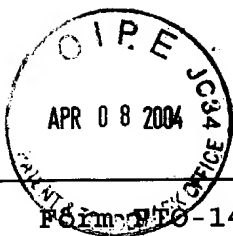
Examiner Initial		Document No.	Date	Name	Class	Subclass
	CA	2002/0022248	2-21-02	Xu et al.	435	69.1

## FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	NO
	CB	WO 00/04149	27-1-00	PCT	x	
	CC	WO 99/64594	16-12-99	PCT	x	

EXAMINER

DATE CONSIDERED



Form PTO-1449 Modified

Docket No.  
DEX-0105Serial No.  
09/700,700List of Patents and Publications  
Cited by Applicant  
(Use several sheets if necessary)Applicant  
Ali et al.

U.S. Department of Commerce

Filing Date  
November 20, 2000Group  
1642

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

DA	Abate-Shen et al., "Nkx3.1; Pten Mutant Mice Develop Invasive Prostate Adenocarcinoma and Lymph Node Metastases <sup>1</sup> ", Cancer Research 2003 63(14):3886-3890
DB	Bierberich et al., "Prostate-specific and Androgen-dependent Expression of a Novel Homeobox Gene", J. Biol. Chem. 1996 271(50):31779-31782 reprinted as pages 1-10
DC	He et al., "A Novel Human Prostate-Specific, Androgen-Regulated Homeobox Gene (NKX3.1) That Maps to 8p21, a Region Frequently Deleted in Prostate Cancer", Genomics 1997 43:69-77
DD	Herbrand et al., "Transcription factors Nkx3.1 and Nkx3.2 (Bapx1) play an overlapping role in sclerotomal development of the mouse", Mechanisms of Development 2002 117:217-224
DE	Kim et al., "Nkx3.1 Mutant Mice Recapitulate Early Stages of Prostate Carcinogenesis <sup>1</sup> ", Cancer Research 2002 62:2999-3004
DF	Kim et al., "Cooperativity of Nkx3.1 and Pten loss of function in a mouse model of prostate carcinogenesis", Proc. Natl. Acad. Sci. USA 2002 99(5):2884-2889 reprinted as pages 1-10
DG	Prescott et al., "Isolation and Androgen Regulation of the Human Homeobox cDNA, NKX3.1", The Prostate 1998 35:71-80
DH	Sciavolino et al., "Tissue-Specific Expression of Murine Nkx3.1 in the Male Urogenital System", Developmental Dynamics 1997 209:127-138
DI	NCBI Genbank Accession U80669 [gi:1732377] 10 December 1996 - 3 June 1999 with Revision History

EXAMINER

DATE CONSIDERED